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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,221	02/16/2001	Doris Hubler	JENA 3	7076

23599 7590 04/27/2007  
MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
2200 CLARENDON BLVD.  
SUITE 1400  
ARLINGTON, VA 22201

EXAMINER
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WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/719,221	<b>Applicant(s)</b> HUBLER ET AL.	
	<b>Examiner</b> Edward J. Webman	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12, 15, 16, 20, 32, 33, 35 and 38-60 is/are pending in the application.
- 4a) Of the above claim(s) 43, 49 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 15, 16, 20, 32, 33, 35, 38-42, 44-48, 51-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Claims 12, 15, 16, 20, 32, 33, 35, 38-42, 44-46, 51-60 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Prophylaxis is synonymous with prevention. Applicants merely show inhibition, and that only under defined *in vitro* and *in vivo* conditions, rather than prevention. Further, nowhere in the specification do applicants define what they experimentally consider as prevention.

Claims 12, 15, 16, 20, 32, 33, 35, 38-42, 44-46, 51-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because applicants' invention does not possess utility regarding prevention, applicants are not enabled for the claimed method of use.

Applicants argue that although they do not provide an explicit definition, the specification clearly teaches the subject and scope of invention. However, applicants have not demonstrated lack of proliferation beyond the time limit set by their experiments. Do applicants intend prevention to mean lack of prevention beyond that time, for example, the lifetime of the organism, a reasonable definition of the term?

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 45, 39-42, 46, 53-54, 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hesch et al (US 5,795,883) in view of Neri (US 3,423,507) .

Hesch et al disclose that it is well known in the art that androgens such as testosterone are useful in methods of treating androgen deficiency in man (column 1, lines 10-16). Such a deficiency is known to cause benign enlargements of the prostate (column 1, lines 46-54). Testosterone propionate is specified (column 1 line 13). However, Hesch et al do not disclose the addition of a gestagen.

Neri teaches cyproterone for treating benign prostate hyperplasia (title, abstract). Tablets are disclosed (column 3 line 12 et seq.)

It would have been obvious to one of ordinary skill to add cyproterone to the androgen deficiency treatment disclosed by Hesch et al to achieve the beneficial effect of treating the accompanying enlargement of the prostate in view of Neri. Given that Neri teaches a tablet, it would be an obvious expedient to deliver both testosterone and cyproterone in such a vehicle.

As to the claimed ranges of androgen and gestagen dosages, it is within the skill of the art to select optimal parameters such as ratios, ranges of doses or

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weight percents of components in order to achieve a beneficial effect. See In re Boesch, 205 USPQ 215 (CCPA 1980). Therefore, the ratios, ranges of doses or weight percents instantly claimed are not considered critical absent evidence showing unexpected and superior results.

Applicants argue that neither reference teaches prophylaxis. However, in light of the rejections under 35 USC 101 and 35 USC 112, the examiner it appears interprets “prophylaxis” to mean “treatment”, in which case the rejection under 35 USC 103 remains apt.

Applicants argue that the examiner is inconsistent in treating the claimed “prophylaxis” as merely a treatment in the art rejection. However, applicants’ data merely show an effect over seven days rather than the lifetime of the organism.

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Richter, can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1500